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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,426	01/24/2007	Hiroshi Yatsuhashi	042715-5016	1411

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EXAMINER

COLEMAN, CHARLES P.

ART UNIT	PAPER NUMBER
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3626

MAIL DATE	DELIVERY MODE
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08/17/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/553,426	Applicant(s) YATSUHASHI ET AL.	
	Examiner CHARLES P. COLEMAN	Art Unit 3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 October 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/1/2008 and 10/18/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

1. This action is in reply to the Application filed on 1/24/2007.
2. Claims 1-16 are currently pending and have been examined.

Information Disclosure Statement

3. The Information Disclosure Statements filed on 10/18/2005 and 4/1/2008 have been considered. Initialed copies of Form 1449 are enclosed herewith.

Priority

4. Applicant's claim for the benefit of prior-filed applications (PCT/JP04/05915, filed 4/23/2004, JAPAN 2003-118496, filed 4/23/2003) under 35 U.S.C. 110(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged.

Abstract

5. The abstract of the disclosure is objected to because the abstract exceeds 150 words in length. Correction is required. See MPEP § 608.01(b).
6. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited.

Claim Rejections - 35 USC § 101

7. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

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8. Claims 1-4 and 8-16 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. A claimed process is eligible for patent protection under 35 U.S.C. § 101 if:

"(1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing. See *Benson*, 409 U.S. at 70 ('Transformation and reduction of an article 'to a different state or thing' is the clue to the patentability of a process claim that does not include particular machines.');

Diehr, 450 U.S. at 192 (holding that use of mathematical formula in process 'transforming or reducing an article to a different state or thing' constitutes patent-eligible subject matter); see also *Flook*, 437 U.S. at 589 n.9 ('An argument can be made [that the Supreme] Court has only recognized a process as within the statutory definition when it either was tied to a particular apparatus or operated to change materials to a 'different state or thing' '); *Cochrane v. Deener*, 94 U.S. 780, 788 (1876) ('A process is...an act, or a series of acts, performed upon the subject-matter to be transformed and reduced to a different state or thing.').⁷ A claimed process involving a fundamental principle that uses a particular machine or apparatus would not pre-empt uses of the principle that do not also use the specified machine or apparatus in the manner claimed. And a claimed process that transforms a particular article to a specified different state or thing by applying a fundamental principle would not pre-empt the use of the principle to transform any other article, to transform the same article but in a manner not covered by the claim, or to do anything other than transform the specified article." (In re *Bilski*, 88 USPQ2d 1385, 1391 (Fed. Cir. 2008))

9. Also noted in *Bilski* is the statement, "Process claim that recites fundamental principle, and that otherwise fails 'machine-or-transformation' test for whether such claim is drawn to patentable subject matter under 35 U.S.C. §101, is not rendered patent eligible by mere field-of-use limitations; another corollary to machine-or-transformation test is that recitation of specific machine or particular transformation of specific article does not transform unpatentable principle into patentable process if recited machine or transformation constitutes mere 'insignificant post-solution activity.'" (In re *Bilski*, 88 USPQ2d 1385, 1385 (Fed. Cir. 2008)) Examples of insignificant post-solution activity include data gathering and outputting. Furthermore, the machine or transformation must impose meaningful limits on the scope of the method claims in order to pass the machine-or-transformation test. Please refer to the USPTO's "Guidance for Examining Process Claims in view of In re *Bilski*" memorandum dated January 7, 2009 .

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10. Claims 1-4 and 8-16 are not tied to a particular machine or apparatus nor do they transform a particular article into a different state or thing, thereby failing the machine-or-transformation test; therefore, claims 1-4 and 8-16 are non-statutory under § 101. The claims as written are directed to non-statutory subject matter.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. Claims 1-7, 9-12 and 14 are rejected under 35 U.S.C. 102(e) as being anticipated by Eils (US 2004/0076984 A1)

CLAIM 1

As per claim 1, Eils teach a disease prognosis prediction modeling method for preparing a model for predicting the prognosis of a specified disease from clinical laboratory test values for the disease by means of a computer, the method comprising the steps of:

- inputting a plurality of actually measured clinical laboratory test values for the disease and actual measured values of the prognoses into the computer; processing these values by a data mining method to determine one or a plurality of clinical laboratory test items which have an influence on the prognosis of the disease; determining a priority of the items with respect to the prognosis in a case where there are a plurality of the items; and establishing a judgment routine in which correlation of the plurality of clinical laboratory test items and the clinical laboratory test value ranges of the test items with the predicted value of the prognosis is stipulated on the basis of the priority, wherein the judgment routine is used as the model (Eils, [0001] and [0002], page 1).

CLAIM 2

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As per claim 2, Eils teach the method of claim 1 and further discloses the limitations of:

- wherein the judgment routine is a decision tree in which a plurality of chance nodes are taken as the clinical laboratory test items and the clinical laboratory test measurement value ranges, and a plurality of prognosis prediction values corresponding to the chance nodes are taken as terminal nodes (Eils, [0001] and [0002], page 1).

CLAIM 3

As per claim 3, Eils teach the method of claims 1 and 2 and further discloses the limitations of:

- predicting the prognosis of a disease from a disease name and the plurality of clinical laboratory test measurement values on the basis of the judgment routine according to claim 1 or claim 2 (Eils, [0001] and [0002], page 1).

CLAIM 4

As per claim 4, Eils teach the method of claims 1 and 2 further discloses the limitations of:

- predicting the prognosis of the disease from clinical laboratory test data using a computer, the method comprising the steps of: storing the judgment routine according to claim 1 or 2 in a computer; inputting a name of the disease which is an object of the prognosis prediction and clinical laboratory test measurement values for the disease into the computer; and determining a predicted value of the prognosis of the disease using the input values on the basis of the judgment routine (Eils, [0001] and [0002], page 1).

CLAIMS 5-7

As per claim 5-7, claims 5-7 are directed to a device. Claims 5-7 recite the same or similar limitations as those addressed above for claims 1-4. Claims 5-7 are therefore rejected for the same reasons set forth above for claims 1-4.

CLAIM 9

As per claim 9, Eils teach the method of claims 3 and 4 and further discloses the limitations of:

- wherein the judgment routine is a decision tree in which a plurality of chance nodes are taken as the clinical laboratory test items and clinical laboratory test measurement value ranges, and a plurality of prognosis prediction values

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corresponding to the chance nodes are taken as terminal nodes (Eils, [0001] and [0002], page 1).

CLAIM 10

As per claim 10, Eils teach the method of claim 9 and further discloses the limitations of:

- wherein the chance nodes of the decision tree comprises patient information (Eils, [0001] and [0002], page 1).

CLAIM 11

As per claim 11, Eils teach the method of claim 2 and further discloses the limitations of:

- a data group which forms the decision tree according to claim 2 (Eils, [0001] and [0002], page 1).

CLAIM 12

As per claim 12, Eils teaches:

- a method for predicting a prognosis relating to a disease of a certain patient from test values for current clinical test items for the disease of the patient by means of a model in which statistical processing is performed on the basis of the relationship between test results, which relate to a plurality of patients, obtained for a clinical test item indicating the disease, and the actual prognoses of the disease for the respective patients (Eils, [0001] and [0002], page 1).

CLAIM 14

As per claim 14, Eils teaches the method of claims 1 and 4 and further discloses:

- wherein the priority of the clinical test items is determined each time in the process of the judgment routine (Eils, [0001] and [0002], page 1).

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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14. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
15. Claims 8, 13 and 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eils (US 2004/0076984 A1), in view of Watanabe et al. (US 5,516,640), as applied to claims 1-7, 9-12 and 14 above.

CLAIM 8

As per claim 8, Eils teach the method of claim 2.

Eils does not teach:

- wherein the disease comprises a liver disease, and the clinical laboratory test item with the highest priority comprises PIVKA.

Watanabe et al. teach:

- wherein the disease comprises a liver disease, and the clinical laboratory test item with the highest priority comprises PIVKA (Watanabe et al., column 1, lines 47-49).

It would have been obvious to one of ordinary skill in the art at the time of the invention to expand the system of Eils to include compatibility with the Health Level 7 transaction data format as recited above. One of ordinary skill in the art at the time of the invention would have been motivated to expand the system of Eils in **because PIVKAs are produced in the blood as a result of hepatocellular carcinoma** (Watanabe et al., column1, lines 47-49).

CLAIM 13

As per claim 13, Eils teach the method of claim 12.

Eils does not teach:

- wherein the clinical test item relates to PIVKA.

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Watanabe et al. teach:

- wherein the clinical test item relates to PIVKA (Watanabe et al., column1, lines 47-49).

The motivation for making this modification to the teachings of Eils is the same as that set forth above in the rejection of claim 8.

CLAIM 15

As per claim 15, Eils teach the method of claims 1 and 4.

Eils does not teach:

- wherein the disease relates to a liver disease, and the highest chance node is set at a critical value relating to the clinical test value of PIVKA.

Watanabe et al. teach:

- wherein the disease relates to a liver disease, and the highest chance node is set at a critical value relating to the clinical test value of PIVKA (Watanabe et al., column1, lines 47-49).

The motivation for making this modification to the teachings of Eils is the same as that set forth above in the rejection of claim 8.

CLAIM 16

As per claim 16, Eils teach the system of claim 13.

Eils does not teach:

- wherein PIVKA reference value is set for each year of survival years when survival predictions in which PIVKA is the node with the highest priority are performed on the basis of the model for each year of survival years.

Watanabe et al. teach:

- wherein PIVKA reference value is set for each year of survival years when survival predictions in which PIVKA is the node with the highest priority are performed on the basis of the model for each year of survival years (Watanabe et al., column1, lines 47-49).

The motivation for making this modification to the teachings of Eils is the same as that set forth above in the rejection of claim 8.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHARLES P. COLEMAN whose telephone number is 571-270-7788. The examiner can normally be reached on Monday through Thursday 7:30am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, CHRISTOPHER (LUKE) L. GILLIGAN can be reached on 571-272-6670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. P. C./
Examiner, Art Unit 3626

/C. Luke Gilligan/
Supervisory Patent Examiner, Art Unit 3626